

REMARKS

Status of the Claims

Claims 1-13 and 15-24 were pending in the application. Applicants elected claims 9-12 (Group II) in response to the Restriction Requirement dated February 7, 2007. Claims 1-8 and 13-24 are withdrawn from consideration, and Applicants reserve the rights to pursue these withdrawn subject matter in a divisional application. New claims 25-26 are added, which represent product claims directed to the novel pharmaceutical preparation. Support for the new claims can be found in the specification (e.g., page 10, lines 29-30 and page 11, lines 1-3). Upon entry of this amendment, claims 9-12, and 25-26 are pending. Applicants respectfully request reconsideration, withdrawal of rejections, and allowance of all pending claims in the application.

Priority

This application is a Continuation application of the parent application (Serial No. 09/944,060) (filed August 31, 2001) and the parent application claims the priority benefit to German Application No. 100 43 509.2 (filed September 1, 2000).

Per Examiner's request, we reviewed our parent file record of 09/944,060. Based on the review, Applicants hereby confirm that a copy of the foreign priority document (i.e., German Application No. 100 43 509.2) was filed via an Express Mail (EL 889408988 US) using Account No. 0691-074. Applicants received the postcard receipt, which contains a confirmation of application serial no. 09/944060 and an official filing date of August 31, 2001. As per Examiner's suggestion, appropriate amendment to the present specification is made.

Specification

Examiner objects the specification as containing a few minor informalities (*See, Office Action, page 3, lines 1-4*). Appropriate correction is made to amend the informalities on page 1 relating the priority year. Accordingly, the objection is considered to be overcome.

Claim Objections

Examiner objects the specification as containing a few minor informalities (*See, Office Action, page 3, lines 5-9*). Appropriate correction is made to amend the claim informalities

relating the term DPI and MDPI. The amendment is merely to clarify the terminology used with no narrowing of any claim scope. No new matter is introduced. Accordingly, the claim objections are considered to be overcome.

Claim Rejections – 35 U.S.C. § 102

Claims 9-12 are rejected under 35 U.S.C. § 102(b) as being unpatentable over U.S. Patent No. 5,993,783 by Eljamal *et al.* (“Eljamal”). According to the Examiner, Eljamal teaches a solid, fine-particulate pharmaceutical preparation for inhalatory administration comprising insulin in e.g., a dry powder inhaler or blister inhaler. Applicants respectfully disagree with Examiner’s position and believe that Eljamal does not teach the present claimed invention.

Without agreeing to the merit of the Examiner’s rejection and in order to expedite the prosecution, Applicants amend the claims to more particularly define the claimed invention. Support can be found in the specification (e.g., page 10, lines 29-30, page 11, lines 1-3) and no new matter is added. The amended claims clearly distinguish from Eljamal. Eljamal teaches using spray-dry process to prepare α 1AT dry powder. Because of the harsh process used by Eljamal, there are issues with protein stability and impurity contaminants. As explained in the present specification, the “customary micronization processes such as spray drying … are less suitable … because of stability and contamination problems. (*See*, e.g., page 1, line 29 to page 2, line 4). The present invention address these defects of the prior art by providing a solid, fine-particulate pharmaceutical preparation containing protein substance which has small particle diameter and minimal protein impurities that are highly suitable for inhalation purposes. (*See*, e.g., page 2, lines 4-19).

In view of the foregoing, Applicants respectfully submit that all the rejections have been overcome and Claims 9-12 are novel over Eljamal.

Conclusion

Based on the foregoing amendments and remarks, Applicants respectfully submit that the application is now in proper form for allowance.

Should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, the Examiner is invited to telephone the undersigned.

The Commissioner is authorized to charge any required fees, including any extension and/or excess claim fees, any additional fees, or credit any overpayment, to Goodwin Procter LLP Deposit Account No. 06-0923.

Respectfully submitted for Applicants,

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